

## REMARKS

The amendments above and these remarks are responsive to the final Office action dated December 11, 2006, and support the accompanying Request for Continued Examination as a submission under 37 C.F.R. § 1.114. Claims 5-9, 11, 13-15, and 17-40 are pending in the application. In the Office action, the Examiner rejected each of the pending claims as follows:

- Claims 5-9, 13-15, 17, 18, 20, 27-37, 39, and 40 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,957,953 to DiPoto et al. ("DiPoto");
- Claims 21-26 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,048,344 to Schenk ("Schenk"); and
- Claims 5-9, 11, 13-15, 17-20, and 27-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over DiPoto alone and/or in combination with U.S. Patent Application Publication No. 2002/0095157 A1 to Bowman ("Bowman").

Applicants traverse the rejections, contending that all of the claims are patentable over the cited references. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants want to patent now, applicants have (1) canceled claim 27, 29, and 30, without prejudice, and (2) amended claims 5, 7, 19, 21, 28, 31-33, 35, and 37. However, applicants reserve the right to pursue the original and/or previously presented subject matter of the amended claims and/or canceled claim at a later time. Furthermore, applicants have presented arguments showing that all of the pending claims are patentable over the cited references. Accordingly, applicants respectfully request reconsideration of the application in view of the amendments

above and the remarks below, and prompt issuance of a Notice of Allowability covering all of the pending claims.

*I. Request for Continued Examination*

Applicants are submitting herewith a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114. This Request complies with the requirements of 37 C.F.R. § 1.114. In particular:

- (i) Prosecution in the application is closed, since the last Office action was a final Office action under 37 C.F.R. § 1.113.
- (ii) The Request is accompanied by a submission as set forth at 37 C.F.R. § 1.114(c), specifically, the amendments and remarks set forth herein.
- (iii) The Request is accompanied by the fee set forth at 37 C.F.R. § 1.17(e).

Accordingly, applicants respectfully request grant of their Request for Continued Examination.

*II. Amendments to the Claims*

The present communication amends 5, 7, 19, 21, 28, 31-33, 35, and 37. The amendments to the claims are supported fully by the application. Exemplary support (or an explanation) for each claim amendment is included, without limitation, in the following table:

<b>Claim</b>	<b>Exemplary Support (or Explanation)</b>
5 (Independent)	Figures 1 and 3; Page 5, line 21
7	Page 6, lines 3 and 4
19	Page 9, line 17

Claim	Exemplary Support (or Explanation)
21 (Independent)	Figures 1 and 3; Page 5, line 21:
28 (Independent)	Page 4, lines 18-21; Page 7, lines 11-15; Page 10, lines 7-17; Page 11, lines 4-6; Page 18, lines 6 and 7 Figures 1, 3, 6, and 7
31	(clarifies reference to step of advancing in claim 28)
32	(clarifies reference to step of advancing in claim 28)
33	(addresses formal issue created by amendment of claim 28)
35	Figures 1 and 3; Page 5, line 21
37	(clarifies meaning of "portion of a circle")

### **III. *Claim Rejections – 35 U.S.C. §§ 102 and 103***

The Examiner rejected each of the pending claims as being anticipated and/or obvious. Applicants traverse the rejections, contending that the cited references, taken alone or in combination, do not teach or suggest every element of any of the rejected claims. Nevertheless, for the reasons set forth above, applicants have amended or canceled every independent claim. Each of the pending claims is patentable for at least the reasons set forth below.

A. Claims 5-9, 11, 13-15, 17-20 and 34

Independent claim 5, as amended, reads as follows:

5. (Currently Amended) A bone screw for compression of a bone, comprising:

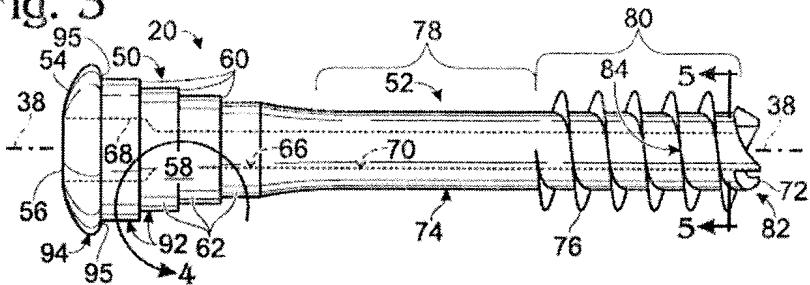
a shank including a thread disposed externally for threaded engagement with bone, the shank [[and]] defining a long axis and a direction of advancement into bone; and

a head connected to the shank and defining a plurality of ledge structures disposed at spaced positions along the head, each ledge structure facing generally toward the direction of advancement and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis.

In the Office action, claim 5 was rejected as being anticipated by Dipoto, obvious over DiPoto, and obvious over DiPoto in view of Bowman. However, none of the cited references, taken alone or in combination, teaches or suggests every element of amended claim 5. For example, neither DiPoto nor Bowman teaches or suggests a bone screw with the recited combination of "a shank including a thread disposed externally for threaded engagement with bone" and "a head connected to the shank and defining a plurality of ledge structures" with each ledge structure extending "to define a respective plane disposed orthogonally to the long axis" defined by the shank.

Figure 3 of the present application shows an exemplary embodiment of a bone screw 20 having all of the elements of claim 5. The figure is reproduced below to facilitate review and comparison with the cited references.

Fig. 3



Exemplary bone screw 20 includes a shank 52 with a thread 76 disposed externally for threaded engagement with bone. The bone screw also includes a head 50 with a plurality of ledge structures 60. Each ledge structure defines a plane that is orthogonal to long axis 38.

Dipoto relates to an expandable suture anchor. Figures 9 and 9A of DiPoto illustrate a suture anchor 200 referred to by the Examiner in rejecting claim 5. These figures are reproduced here to facilitate review:

FIG. 9

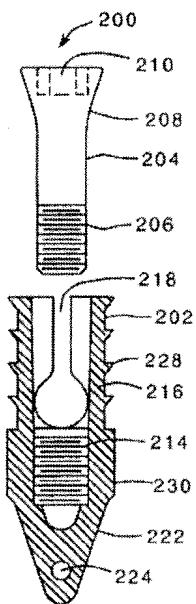
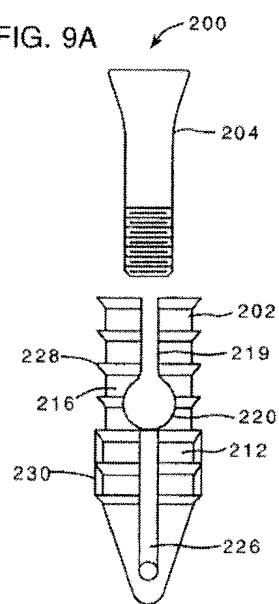


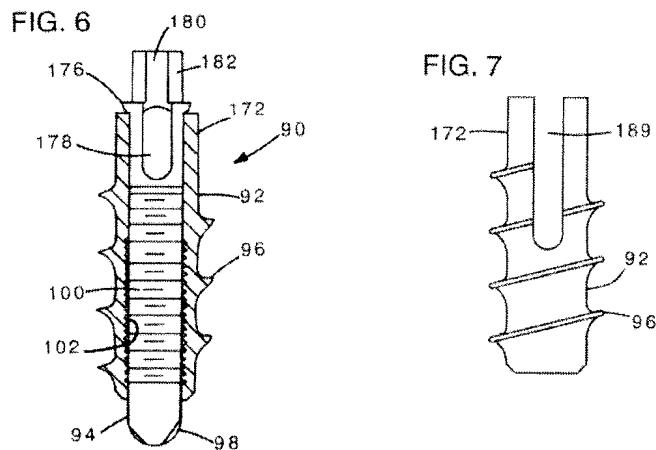
FIG. 9A



Anchor 200 is composed of "an expandable outer anchoring member 202 and an inner member 204 for which is threaded into outer member 202 to adjustably expand outer member 202" (col. 9, lines 15-18). More particularly, the inner member has a

threaded distal section 206 that threads into a threaded bore 214 of the outer member, in a position spaced from bone. Accordingly, neither the inner member nor the outer member has “a thread disposed externally for threaded engagement with bone,” as recited by amended claim 5. Instead, the outer member engages bone via transverse ridges 228 and axial ridges 230, neither of which is formed as a thread. In fact, the axial ridges are disclosed to resist rotation of the outer member relative to bone, thereby precluding the use of thread for threaded engagement with bone in this embodiment. Furthermore, the axial ridges, by resisting rotation, direct translational insertion of anchor 210 into a hole in bone.

Figures 6 and 7 of DiPoto illustrate an expandable suture anchor 90 that threads into bone. These figures are reproduced here to facilitate review.



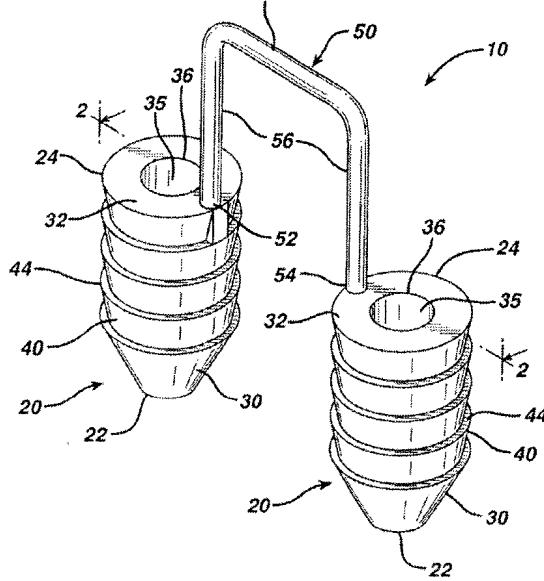
Outer member 92 has a thread 96 that taps bone as the outer member is rotated into bone. The thread is disclosed to extend into the expandable portion of the outer member. Accordingly, thread 96 replaces the transverse and axial ridges present in anchor 210 (see above), and replaces translational installation into bone with rotational installation. As a result, anchor 90 does not include a head defining a

plurality of ledge structures, with each ledge structure extending “to define a respective plane disposed orthogonally to the long axis” defined by the shank, as recited by claim 5.

DiPoto does not disclose any embodiments of the anchor that include both an external thread and transverse ridges on the outer member and it would not have been obvious to make this combination. In particular, the external thread and transverse/axial ridges of DiPoto are disclosed to function as alternative structures for engagement with bone. In the anchors and installation approaches disclosed by DiPoto these alternative structures apparently are incompatible with one another.

Bowman relates to a graft fixation device. Figure 1 illustrates an embodiment of the device and is reproduced here to facilitate review:

FIG. 1



Graft device 10 includes a pair of implantation members 20 with projections 40 having tissue engagement edges 44. In some embodiments, the graft device has only one implantation member. However, Bowman does not teach or suggest the

device having a thread disposed externally for threaded engagement with bone, as recited by amended claim 5. Accordingly, even if it would have been obvious to combine DiPoto with Bowman, and applicants contend that it would not have been, this combination does not result in the same bone screw including the recited thread and the recited ledge structures. More particularly, neither reference teaches or suggests a thread and ledge structures, as recited, functioning together in the same bone screw.

In summary, neither DiPoto nor Bowman, taken alone or in combination, teaches or suggests every element of amended claim 5. Claim 5 thus should be allowed. In addition, claims 6-9, 11, 13-15, 17-20, and 34, which depend from claim 5, also should be allowed for at least the same reasons as claim 5.

B. Claims 21-26

Independent claim 21, as amended, reads as follows:

21. (Currently Amended) A bone screw for compression of a bone, comprising:

a shank including a proximal region, a distal region, and a thread **disposed externally for threaded engagement with bone and** restricted to the distal region; and

a head connected to the shank and spaced from the thread by the proximal region, the head including a lateral surface defining a plurality of spaced ledge structures disposed **along** [[on]] the head, each ledge structure **extending in a respective plane to describe** describing at least **an arc** a portion of a circle.

In the Office action, claim 21 was rejected as being anticipated by Schenk. However, Schenk does not teach or suggest every element of claim 21. For example, Schenk

does not teach or suggest a bone screw comprising a shank with "a thread disposed externally for threaded engagement with bone" and a head defining a plurality of spaced ledge structures with "each ledge structure extending in a respective plane to describe at least an arc of a circle."

Schenk relates to a threaded washer and bone screw apparatus. Figure 4 illustrates an example of the apparatus and is reproduced here to facilitate review:

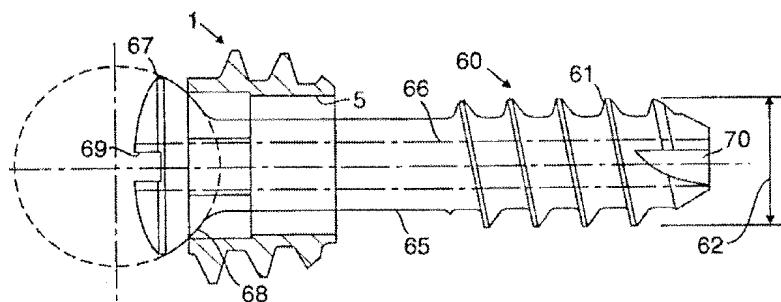


FIG. 4

The apparatus is disclosed to include a cannulated screw 60 and a threaded washer 1 with a central unthreaded bore 5 that receives the cannulated screw. Figure 8 of Schenk illustrates the apparatus installed in bone and is reproduced here to facilitate review:

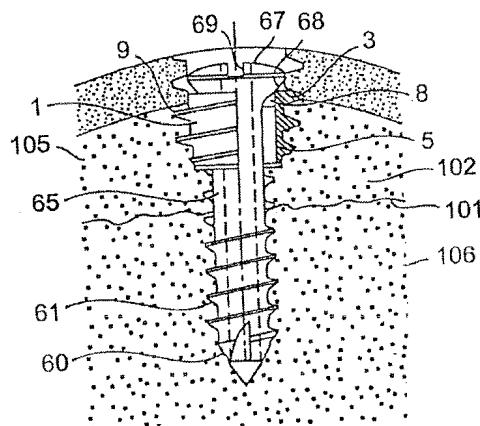


FIG. 8

Threaded washer 1 has an external thread 9 that allows the threaded washer to be driven rotationally into bone. Thread 9 winds around and along the exterior of the cylindrical body of the threaded washer, to follow a helical path that is inherently nonplanar and noncircular.

In the Office action, the Examiner stated that the “ledge structures” (thread 9) of Schenk “all comprise at least one point, which can be considered to be a portion of a circle” and also “describe complete circles, since, as viewed from a top-down perspective along a long axis, the ledge structures appear to form a circle” (page 7, lines 5-9). Applicants suggest that the Examiner has adopted an interpretation of the claim language at odds with normal usage. However, in a spirit of cooperation and in an attempt to clarify the intended meaning of the claim language, applicants have amended claim 21 by replacing “each ledge structure describing at least a portion of a circle” with “each ledge structure extending in a respective plane to describe at least an arc of a circle.” The screw and washer of Schenk each have a helical thread and thus Schenk does not disclose a bone screw with the recited ledge structures.

In summary, Schenk does not teach or suggest every element claim 21 and thus claim 21 should be allowed. In addition, claims 22-26, which depend from claim 21, also should be allowed for at least the same reasons as claim 21.

C. Claims 28 and 31-33

Independent claim 28, as amended, reads as follows:

28. (Currently Amended) A method of compressing a bone with a bone screw, comprising:

forming a hole in the bone;

selecting a bone screw having a shank and a head connected to the shank, the head defining a plurality of ledge structures disposed at spaced positions along the head, each ledge structure facing generally toward the direction of advancement and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis; and

advancing first the shank and then the head of the bone screw into the hole via threaded engagement of the shank with bone so that the head contacts and applies an axial force selectively to a plurality of spaced annular regions of the bone that each define a respective plane, such that a portion[[s]] of the bone near the head is [[are]] compressed toward a portion[[s]] of the bone near the shank.

In the Office action, claim 28 was rejected as being anticipated by DiPoto and as being obvious over DiPoto alone and in combination with Bowman. However, the cited references, taken alone or in combination, do not teach or suggest every element of claim 28. For example, and for the same general reasons as those presented above in relation to claim 5, neither reference teaches or suggests (1) selecting a bone screw having a head defining a plurality of ledge structures, with each ledge structure extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis, and (2) advancing the bone screw via threaded engagement of the shank of the bone screw with bone. Instead, the cited references disclose threaded engagement with bone or engagement with

bone via transverse ridges, but not both at the same time. Claim 28 thus should be allowed. In addition, claims 31-33, which depend from claim 28, also should be allowed for at least the same reasons as claim 28.

*D. Claims 35-40*

Claim 35, as amended, reads as follows:

35. (Currently Amended) A bone screw for compression of a bone, comprising:

a shank including a thread disposed externally for threaded engagement with bone, the shank [[and]] defining a long axis and a direction of advancement into bone; and

a head connected to the shank and including a plurality of spaced shoulders of different diameter, each shoulder facing generally in the direction of advancement and extending partially or completely around the long axis in a respective path defining a plane.

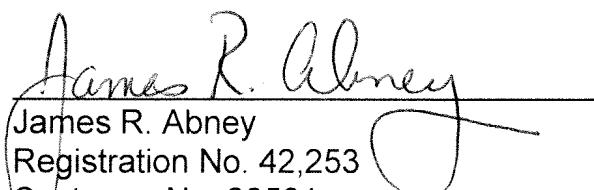
In the Office action, claim 35 was rejected as being anticipated by DiPoto and as being obvious over DiPoto alone and in combination with Bowman. However, the cited references, taken alone or in combination, do not teach or suggest every element of claim 35. For example, and for the same general reasons as those presented above in relation to claim 5, neither reference teaches or suggests “a shank including a thread disposed externally for threaded engagement with bone,” and a head including a plurality of spaced shoulders of different diameter, with each shoulder “extending partially or completely around the long axis in a respective path defining a plane.” Claim 35 thus should be allowed. In addition, claims 36-40, which depend from claim 35, also should be allowed for at least the same reasons as claim 35.

**IV. Conclusion**

Applicants believe that each of the pending claims is patentable over the cited references. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering all of the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record, or his associate Stan Hollenberg (Reg. No. 47,658), both at 503-224-6655.

Respectfully submitted,

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